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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,669

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Mitta Suresh

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35690

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MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.

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EXAMINER

LANG, AMY T

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

10/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/790,669	Applicant(s) SURESH ET AL.	
	Examiner AMY T. LANG	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,8-28,53,75,97,116, and 140 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,8-28,53,75 and 140 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Election/Restrictions

2. Applicant's election without traverse of Invention I in the reply filed on 07/15/2008 is acknowledged.
3. Claims 97 and 116 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/15/2008.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1, 2, 5, 6, 8-26, 28, 53, and 140** are rejected under 35 U.S.C. 102(e) as being anticipated by Khairkhahan et al. (US 2002/0111647 A1).

With regard to **claims 1, 5, 8, and 15**, Khairkhahan et al. (hereinafter Khairkhahan) discloses an apparatus comprising a reinforcing element (11) configured to reinforce a portion of an endocardial surface (see entire document; Figure 1). The element (11) is movable between a reduced, first predetermined shape and an expanded, second predetermined shape ([0060]). An adjustment mechanism is utilized to expand the device while in a patient's body so that the reinforcing element is configured to change from the first shape to the second while in a ventricle of the patient's heart ([00796]). The adjustment mechanism is further disclosed as a pullwire that is activated by a user ([0076]). Therefore, there inherently exists an infinite number of cross-sectional profiles of the reinforcing element between the fully reduced, first predetermined shape and the fully expanded, second predetermined shape so that user is able to adjust the adjustment mechanism to a third shape.

Although Khairkhahan does not specifically disclose the reinforcing element for use in an endocardial surface of a ventricle, specifically scar tissue, this is an intended use phrase and therefore given minimal patentable weight. The examiner's position is supported by case law, which holds that "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation." *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) and MPEP 2111.02.

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Additionally, the apparatus of Khairkhahan is capable of attaching to a portion of a patient's ventricle and thereby prevent that portion of the ventricle from expanding.

Anchors (195) allow the reinforcing element to attach to an endocardial surface of the patient's ventricle and prevent the surface from expanding ([0055]; Figure 7A). It is the examiner's position that normal contraction and expansion during the cardiac cycle of the patient's heart is not affected with the reinforcing element, absent evidence to the contrary.

After the reinforcing element is attached to the patient's endocardial surface through anchors (195), adjusting the pullwire to change the shape of the element would also pull on the patient's ventricle and change its dimension. Since the anchor is embedded in the endocardial surface of the ventricle, reducing the diameter of the reinforcing element would cause the anchor to pull the endocardial surface inward and change the dimension of a portion of the ventricle. Therefore, the adjustment mechanism is configured to change from the second shape to the third, after attaching the anchors, and thereby change a dimension of a portion of the ventricle.

With regard to **claim 2**, since Khairkhahan teaches the same apparatus as claimed comprising a reinforcing element having a first and second predetermined shape, it is the examiner's position that the apparatus is configured to inhibit expansion of an average of an endocardial surface over a cardiac cycle of the left or right ventricle.

With regard to claims **6 and 10**, Khairkhahan further discloses the reinforcing element having anchors (195) for attachment to tissue ([0055]; Figure 7A). Therefore, the reinforcing element is configured to releasably attach to the endocardial surface of a

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ventricle of the heart through the anchors. Furthermore, the anchors clearly overlap the instantly claimed activation mechanism since they are configured to attach the reinforcing member to an endocardial surface.

With regard to **claim 9**, Khairkhahan also teaches a locking mechanism that inhibits movement of the adjustment mechanism ([0076]). Therefore, the locking mechanism of Khairkhahan clearly overlaps the instantly claimed engagement mechanism.

With regard to **claim 11**, the reinforcing element comprises a frame (14) with a porous patch network (15) ([0044], [0047]). Therefore, component 15 clearly overlaps the instantly claimed patch.

With regard to **claim 12**, it is the examiner's position that the second predetermined shape of Khairkhahan substantially emulates the shape and size of a portion of the left ventricle.

With regard to **claims 13 and 14**, the frame (14) of the reinforcing member is comprised of Nitinol ([0046]).

With regard to **claims 16, 26, 28, and 53**, the frame (14) comprises metal spokes (17), which overlap the instantly claimed plurality of conduits ([0044]; Figure 1). Anchors (195) are attached to the spokes and extend distally beyond the conduits ([0055]; [0057]).

With regard to **claim 17**, it is the examiner's position that spokes 17 and 196 overlap the claimed conduits so that Khairkhahan teaches a plurality of conduits with variable length (Figure 1).

With regard to **claims 18 and 19**, Khairkhahan teaches the elongated member as anchors, barbs, hooks, or pins, which are all configured to change shape upon extending beyond the corresponding conduit ([0058]).

With regard to **claims 20 and 21**, it is the examiner's position that the outer rim of frame (14) couples conduits (17) together and overlaps the instantly claimed support element (Figure 1). The outer rim also limits the expansion of the reinforcing element to the second predetermined shape. Furthermore, member 16 couples conduits 196 with conduits 17 and therefore also overlaps the instantly claimed support element (Figure 1).

With regard to **claims 22 and 23**, as shown in Figure 1, the conduits radiate outward from a center region so that the center region (196) couples the conduits together.

With regard to **claims 24 and 25**, the device comprises lumen (322) for positioning a guidewire ([0083]; Figure 19).

With regard to **claim 140**, as shown in Figure 1, the shape of the reinforcing member is similar to a shape and size of a portion of the left ventricle.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 27 and 75** are rejected under 35 U.S.C. 103(a) as being unpatentable over Khairkhan (US 2002/0111647 A1).

Khairkhan discloses a reinforcing element for reinforcing a portion of a patient's heart. As shown in Figure 19, the apparatus comprises a lumen (322) for positioning a guidewire ([0083]; Figure 19). Although the guidewire, does not extend beyond the distal end of the reinforcing element, this limitation would have been obvious at the time of the invention. It is well known in the art for guidewires to extend beyond the distal end of devices when inserted into a patient's vasculature to facilitate entry into the curving vasculature. Additionally, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the apparatus. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Response to Arguments

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9. Applicant's arguments filed 10/31/2007 have been fully considered but they are not persuasive.

Specifically, applicant argues (A) that Khairkhahan appears to teach a device that functions to resist compression and not one that is configured to reinforce at least a portion of an endocardial surface.

With respect to argument (A), as discussed above, Khairkhahan discloses a device that meets the claimed structural limitations and is therefore configured to reinforce a portion of an endocardial surface. As long as the prior art meets the structural requirements and is capable of performing the functions, the prior art meets the limitations.

Specifically, applicant argues (B) that Khairkhahan does not teach an elongated member that engages an endocardial surface.

With respect to argument (B), anchors (195) of Khairkhahan overlap the instantly claimed extendable members. As shown in Figure 7B, the anchors extend out of the conduits to engage an endocardial surface.

Specifically, applicant argues (C) that Khairkhahan does not teach a device wherein the third shape is similar to the shape and size of a portion of the left ventricle.

With respect to argument (C), the instant specification teaches that a conical or tear drop is a sufficient shape that is similar to a portion of the left ventricle. As shown in Figures 1 and 2 of Khairkhahan, the device is conical and of a tear drop shape so that

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it is also similar to a portion of the left ventricle. Additionally, it is the examiner's position that the size and shape of Khairkhahan is sufficient since a portion of a left ventricle is extremely vague and does not define a specific shape or size.

10. Applicant's arguments, filed 10/31/2007 with respect to Macoviak et al. (US 2002/0143362 A1) have been fully considered and are persuasive. The rejections have been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/06/2008

/Amy T Lang/

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731